IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gholam-Reza Zadno-Azizi, *et al.*
Serial No.:	10/081,569
Conf. No.:	4156
Filed:	February 21, 2002
For:	*BODY FLUID FLOW CONTROL DEVICE*
Art Unit:	3738
Examiner:	Urmi Chattopadhyay

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JAMES I. FANN, M.D. UNDER 37 C.F.R. §1.132

I, James I. Fann, M.D., do hereby declare as follows:

1. I currently hold the position of Associate Professor in the Department of Cardiothoracic Surgery at the Stanford University School of Medicine. I am also currently a staff surgeon for Veterans Affairs Health Care System, Section of Cardiothoracic Surgery in Palo Alto, California, a position I have held since 1996. I am also currently a staff surgeon at El Camino Hospital in Mountain View, California, a position I have held since 2002. A copy of my *curriculum vitae* is attached hereto as Exhibit 1.

The '569 Application

2. I have reviewed the above-captioned patent application, U.S. Patent Application Serial No. 10/081,569 (the '569 application), including claims 16-19.

3. I am aware of the U.S. Patent Office rejection of claims 16-19 of the '569 application under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt *et al.* (the "Leonhardt patent") in view of U.S. Patent No. 5,411,552 to Andersen *et al.*.

The Leonhardt Patent

4. The Leonhardt patent describes a valve stent 20 (the "Leonhardt valve stent") comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. (Leonhardt, 4:14-16.) The biological valve 22 is attached to the stent 26 and/or to the graft material 24 with sutures or with a biocompatible adhesive. (Leonhardt 6:25-27.) The graft material 24 is a low-porosity woven fabric (Leonhardt, 5:53-54). In addition, the graft material 24 is attached to the stent 26 by sewing the graft material 24 to the stent 26 using polyester suture. (Leonhardt, 5:36-37; 5:62-6:8.)

5. It is my expert opinion that the Leonhardt valve stent is unsuited for use in a bronchial sub-branch. It is my expert opinion that the Leonhardt valve stent, if sized to be used in a bronchial sub-branch and placed in a bronchial sub-branch communicating with a portion of a lung, would not preclude inhaled air from flowing into the portion of the lung. Consequently, placement of the Leonhardt valve stent in such a bronchial sub-branch would fail to result in collapse of the lung portion and reduction in the size of the lung. This is because the Leonhardt valve stent is constructed such that it would leak air.

6. One reason that the Leonhardt valve stent would leak air is that the graft material used in the Leonhardt valve stent is a low-porosity woven fabric, such as polyester or PTFE. Although Leonhardt states that the graft material is "low-porosity", it is my expert opinion that any porosity whatsoever

would result in an air leaks across the Leonhardt valve stent. Moreover, the weaves in the woven fabric create additional leak paths through which air can flow. Thus, it is my expert opinion that if a bronchial obstructing device having a graft made of a low-porosity woven fabric were placed in the lung, the porous and woven nature of the graft would result in air leakage across the device. Because air would leak across such an obstructing device, the obstructing device would not preclude inhaled air from flowing into the lung and would not result in collapse of the lung or reduction in the size of the lung.

7. Another reason that the Leonhardt device would leak air is that the sutures sewed into the graft material would form multiple holes in the graft material at the various stitch points between the suture and the graft material. The suture holes formed in the graft material would create multiple leak paths through which air could pass through the Leonhardt device. Thus, it is my expert opinion that an obstructing device in which a graft was sutured to a stent would leak air and, therefore, would fail to preclude inhaled air from flowing into the lung and fail to result in collapse of the lung and reduction in the size of the lung.

8. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

8-22-04
Date

James I. Fann, M.D.